IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Thomas Dietz, et al.

Examiner: Shengjun Wang

Serial No: 09/777,544

Art Unit: 1617

Filed: February 6, 2001

Docket: 14186

For: COSMETIC AND PHARMACEUTICAL OIL-IN-WATER EMULSIONS

Confirmation No. 7213

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**DECLARATION OF THOMAS DIETZ UNDER 37 C.F.R. §1.132**

Sir:

I, Thomas Dietz, hereby declare and say that:

(1) Peter Hameyer, Klaus Jenni and myself are the applicants named in U.S. Application Serial No. 09/777,544, filed with the United States Patent and Trademark Office on February 6, 2001.

(2) I am familiar with the subject matter disclosed in U.S. Application Serial No. 09/777,544 and have reviewed the applied reference, namely U.S. Patent No. 6,488,780 to Cauwet-Martin that was cited in the Office Action dated July 13, 2004.

(3) I understand from reviewing said Office Action that the emulsion composition disclosed in Example 8 of the originally filed specification was determined to be allowable over the Cauwet-Martin reference. In Example 8, the polyether siloxane of Reference Example 3 (also of the original application) was used to make a stable oil-in-water emulsion. By 'stable', it is meant that the emulsion is homogeneous exhibiting no phase separation even after an extended period of time which is appropriate in pharmaceutical or cosmetic uses. As

indicated at paragraph [0033] of the printed U.S. Patent Application Publication No. 2001/0046507, which corresponds to U.S. Application Serial No. 09/777,544, such a result is surprising since it was not known that the polyether siloxanes as defined in Claim 1 of the present application could provide stable emulsions without substantially disturbing the consistency imparting structures present in the emulsion. In contrast, customary polyether siloxanes that are outside those defined in Claim 1 of the present invention are known to disturb those structures. I also understand that during a telephonic interview with my representative, the Examiner indicated that broader coverage was possible, if additional experimentation was performed showing that a stable emulsion could be produced for different emulsion compositions that include other polyether siloxanes as defined by Claim 1 of the present application.

(4) In view of the above, additional experiments and data have been carried out to establish that the claimed oil-in-water emulsions of the present application are not obvious relative to the disclosure of Cauwet-Martin.

(5) The experiments performed and reported in this Declaration were conducted by me or under my direct supervision or control.

(6) Specifically, the following experiments show emulsion stability at room temperature and at elevated temperature when the polyether siloxane as defined by Claim 1 was used as the emulsifier relative to prior art emulsions in which polyether siloxanes that fall outside the definition of Claim 1 are used. The polyether siloxanes of the present invention that were used in preparing the stable oil-in-water emulsions are shown in Table 1 below. These polyether siloxanes, which are labeled as Reference Examples A-D, all satisfy the definition of the polyether siloxane identified in Claim 1.

Table: 1:

| Ref. Example | n | $MW_{silicone\ radical}$ | m | x | y | z | $MW_{polyether\ radicals}$ | Proportion by weight of polyether radicals in [%]* |
|---|---|---|---|---|---|---|---|---|
| A | 100 | 7542 | 3 | 11 | 17 | 1 | 3058 | 29 |
| B | 80 | 6060 | 3 | 9 | 0 | 1 | 910 | 13 |
| C | 80 | 6060 | 3 | 23 | 0 | 1 | 2142 | 26 |
| D | 80 | 6060 | 3 | 26 | 4 | 1 | 2870 | 32 |

*calculated according to formula (II) which appears in paragraph [0021] of printed U.S. Patent Application Publication No. 2001/0046507, which corresponds to U.S. Application Serial No. 09/777,544.

In the examples provided in Table 1, a z value of 1 denotes that $R^1$ is H, a z value of 15 denotes that $R^1$ is $CH_3$, and a z value of 29 denotes that $R^1$ is $CH_2CH_3$. It is noted that Reference Examples A-D cover a wide range (between 13%-32% proportion by weight) of polyether, which falls within the range recited in Claim 1 of the present application.

(7) In the present experiments, the polyether siloxanes of Reference Examples A-D were tested in separate oil-in-water emulsions that were based on the experimentation described in Example 8 of the originally filed application. Two commercial silicone polyethers (Silwet types from GE Silicones), Comp. 3 and Comp. 4, which fall within the silicone compound of formula (I) of Cauwet-Martin, were also tested for comparison. The commercial silicone polyethers have a polyether portion of 75%, which is outside the range recited in Claim 1 of the pending application.

Specifically, oil-in-water emulsions were prepared using the procedure described in Example 8 of the originally filed application, with the exception that the polyether siloxane of Reference Example 3 was replaced with the polyether siloxanes of Reference Examples A-D.

In accordance with that example, Phase A and Phase B (See Table 2 below for the components present in Phases A and B) were heated separately to 70°C and combined, and the mixture was intensively homogenized for 1 minute. The homogenized mixture was then cooled in a water bath and stirred. For stability testing, 50 gram samples were stored in closed glass jars at room temperature and at 40°C. Stability testing at 40°C was performed as an industrial standard, i.e., to test emulsions at a standard elevated temperature. Moreover, the elevated temperature accelerates such testing without substantially impacting the results thereof.

Table 2 Examples 8,15-18, comparative examples 3 and 4:

| | Examples | Comp.3 | Comp.4 | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|---|---|
| A | Polyether siloxane Reference example A | - | - | 1.8% | - | - | - | - |
| | Polyether siloxane Reference example 3 (reproduced from original Example 8) | - | - | - | 1.8% | - | - | - |
| | Polyether siloxane Reference example B | - | - | - | - | 1.8% | - | - |
| | Polyether siloxane Reference example C | - | - | - | - | - | 1.8% | - |
| | Polyether siloxane Reference example D | - | - | - | - | - | - | 1.8% |
| | Silwet L-722* | 1.8% | - | - | - | - | - | - |
| | Silwet L-7500** | - | 1.8% | - | - | - | - | - |
| | Ceteareth-25 | - | 0.2% | 0.2% | 0.2% | 0.2% | 0.2% | 0.2% |
| | Glyceryl stearate | 2.0% | 2.0% | 2.0% | 2.0% | 2.0% | 2.0% | 2.0% |
| | Stearyl alcohol | 1.0% | 1.0% | 1.0% | 1.0% | 1.0% | 1.0% | 1.0% |
| | Mineral oil | 5.0% | 5.0% | 5.0% | 5.0% | 5.0% | 5.0% | 5.0% |
| | Ethylhexyl stearate | 5.0% | 5.0% | 5.0% | 5.0% | 5.0% | 5.0% | 5.0% |
| | Isopropyl palmitate | 5.0% | 5.0% | 5.0% | 5.0% | 5.0% | 5.0% | 5.0% |
| B | Glycerol | 2.0% | 2.0% | 2.0% | 2.0% | 2.0% | 2.0% | 2.0% |
| | Water | 80.0% | 80.0% | 80.0% | 80.0% | 80.0% | 80.0% | 80.0% |

*Silwet L-722 (GE Silicones/OSi Specialties): Terminally modified polyether siloxane with a proportion by weight of the polyether radicals of 75 %.

**Silwet L-7500 (GE Silicones/OSi Specialties): Comb-like polyether siloxane with a proportion by weight of the polyether radicals of 75 %.

(8) The emulsions of Examples 1-5 were characterized by a smooth and homogeneous appearance after preparation. No phase separation was observed after preparation. These

emulsions were stable at room temperature and at 40°C. Again, no phase separation was observed within the time period that the emulsions were examined. The emulsions of Comp. Examples 3 and 4 showed water separation at 40°C after four days. Thus, Comp. Examples 3 and 4 provided instable emulsions. The additional data provided in this document shows that creams containing the polyether siloxanes of Reference Examples A-D including Example 2 result in stable emulsions. In contrast, the creams containing the polyether siloxanes Silwet L-722 and Silwet L-7500 result in unstable emulsions. Comb-like polyether siloxanes which also are covered in formula I of Cauwet-Martin were previously shown in the pending application to provide an unstable emulsion.

(9) The data provided herein, together with that previously presented in the pending application, show that the applicants have surprisingly discovered that a class of polyether siloxanes that fall within the definition of Claim 1 can be used to provide oil-in-water emulsions that are stable at room temperature and at elevated temperature relative to other polyether siloxanes that fall outside the definition of the siloxane compound of Claim 1.

(10) All statements made herein, of my own knowledge, are true, and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made may be punishable by fine or imprisonment or both, under Section 1001 Title 18 of the U.S. code and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

Dated: 01/14/05

Thomas Dietz